

REMARKS

In the Claims

Claims 17, 19, 34, and 51 have been canceled herein. Claim 1 has been amended to correct a typographical error. No new matter has been added herein. Claims 1-16, 18, 20-33, and 35-50 are pending.

Response to Restriction Requirement

In the current Restriction Requirement, the Examiner restricted the application and required an election of one of the following five Groups under 35 U.S.C. § 121 and 372:

Group I: Claims 1-16, drawn to a method of making a controlled release composition;

Group II: Claims 17 and claim 34, drawn to a controlled release composition;

Group III: Claims 18, 20-33, and 35, drawn to a process for the production of microparticles and improvements thereof;

Group IV: Claims 36-50, drawn to a method of making a controlled release composition; and

Group V: Claims 19 and claim 51, drawn to a microparticle composition.

As required in response to this Restriction Requirement, Applicant elects Group I, which Claims 1-16 read thereon. This election is made with traverse for the reasons set out below.

The Examiner also required an election of species. Since Applicant has elected Group I (with traverse), the Examiner specifically required an election of species for the (1) cosolvent, (2) emulsifying agent, (3) solvent, (4) controlled release composition, (5) polymer, (6) bioactive agent, (7) protein or peptide, and (8) organic ion. In response, Applicant makes the following species elections, also with traverse.

1. Cosolvent – benzyl alcohol.
2. Emulsifying agent – poly(vinyl alcohol).

3. Solvent –ethyl acetate.
4. Controlled release composition – microparticles.
5. Polymer – typically poly(lactide-co-glycolide)s.
6. Bioactive agent – proteins.
7. Protein or peptide – oxytocin.
8. Organic ion – carboxylate.

Claims 1-16 read on the elected Group I and on the elected species.

As noted above, these elections are made with traverse. For a Restriction Requirement to be proper, the Examiner must satisfy the following criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121); **and** (2) that the search and examination of the entire application cannot be made **without serious burden on the Examiner**. M.P.E.P. § 803 provides:

If the search and examination of an entire application can be made without serious burden, the Examiner **must** examine it on the merits, even though it includes claims to distinct or independent inventions. (Emphasis added.)

Applicant respectfully submits that there has been no showing that it would be a serious burden to search and examine the five groups together. As evidenced by the International Search Report (form PCT/ISA/210) and the International Preliminary Examination Report (form PCT/ISA/237), the international Examiner searched and examined all the claims (1-51) during the international phase. Thus, the examination of Claims 1-51 in the present national phase application cannot reasonably be construed to impose an undue burden on the Examiner.

Furthermore, the Examiner cited Claim 17 and alleged that the Restriction Requirement was proper under PCT Rule 13.1 because the single inventive concept was simply a composition comprising a bioactive agent, polymer, and organic salt. This is incorrect. The compositions disclosed and claimed are prepared by processes that utilize an organic ion. This technical feature results in compositions that have different degrees of loading and different release profiles, than those formed without the organic ion. In fact, this is exemplified in the many examples of the application.

Moreover, Applicants have canceled the composition claims herein (Claims 17, 19, 34, and 51), without prejudice to refile in a divisional application. Thus, the technical feature identified by the Examiner as failing to satisfy PCT Rule 13.2 (which is wrongly stated to be a composition of merely a polymer, active, and organic salt) is moot. The claims that are now pending are method claims that all recite the use of an organic ion in the aqueous phase. The art cited by the Examiner does not. Therefore, having this common technical feature, the restriction of the pending claims is improper and should be withdrawn.

In conclusion, for the reasons stated above, Applicant respectfully asserts that restriction of the claims as set forth by the Examiner would be contrary to promoting efficiency, economy and expediency in the Patent Office and further point out that restriction by the Examiner is discretionary (M.P.E.P. § 803.01). Examining all of the claims together would eliminate the necessity of prosecuting multiple, separate, yet intimately related applications. Thus, Applicant respectfully requests that all of the claims of this application be examined together. Consequently, reconsideration and modification or withdrawal of the restriction requirement is requested.

CONCLUSION

Enclosed herewith is payment in the amount of \$130.00 for the fee under 37.C.F.R. §1.17(a)(1) for the One-Month Extension of Time. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

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Respectfully submitted,

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CERTIFICATE OF EFS-WEB SUBMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included is being submitted electronically via EFS-WEB submission, on the date indicated below.

/Christopher L. Curfman/

February 9, 2009

Christopher L. Curfman

Date